K040542 pg 1 of 2

AUG 1 9 2004

We are smith&nephew

Endoscopy Division
Smith & Nephew, Inc.
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Andover, MA 01810

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SECTION IV
510(k) SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION

as required by the Safe Medical Devices Act of 1990 and codified in 21 CFR 807.92 upon which the substantial equivalence is based.

The Smith & Nephew GTS Sleeve and GTS Tapered Screw
Date Prepared: 1 March 2004

A. Submitter's Name:

Smith & Nephew, Inc., Endoscopy Division
150 Minuteman Road
Andover, MA 01810

B. Company Contact

Marion W. Gordon, RAC
Regulatory Affairs Specialist
Phone: 978-749-1371 Fax: 978-749-1443

C. Device Name

Trade Name:	The Smith & Nephew GTS Sleeve and GTS Tapered Screw
Common Name:	Fixation, bone, screw
Classification Name:	Smooth or metallic bone fixation fastener per 21 CFR § 888.3040

D. Predicate Devices

The Smith & Nephew GTS Sleeve and GTS Tapered Screw are substantially equivalent to Intrafix™ Tibial Sheath and Intrafix™ Tibial Tapered Screw, manufactured by Innovasive Devices, Inc. (acquired by Johnson & Johnson, November 1999) and found substantially equivalent on 28 January 1999 under K983560. In addition, the proposed GTS Tapered Screw is substantially equivalent to Smith & Nephew, Inc. K032224 (SE 08/05/03) and K992396 (SE 01/12/00) BioRCI® Screws.

E. Description of Device

The Smith & Nephew GTS Sleeve and GTS Tapered Screw consist of two (2) components, the sleeve and screw. The sleeve manages, protects, and separates the graft tendon bundle and creates a central path for concentric placement of the tapered screw, which forces a larger surface area of the tendons against the tibial tunnel wall within a surgically created tunnel.

SECTION IV cont.

F. Intended Use

The Smith & Nephew GTS Sleeve and GTS Screw are indicated for fixation of soft tissue grafts during cruciate ligament reconstruction.

G. Comparison of Technological Characteristics

The proposed Smith & Nephew GTS Sleeve and GTS Tapered Screw and the Intrafix™ Tibial Sheath and Intrafix™ Tapered Screw share the same indications for use and basic fundamental scientific technology. Both employ a multi channeled, single construct device (one channel for central screw placement) to manage, protect and circumferentially compress graft tendons. The tapered screw creates the final fixation within a created tibial tunnel. The bioresorbable GTS Tapered Screw and non-absorbable Intrafix™ Screw have similar geometries and range of sizes. Each device is packaged as single patient use and EO sterilized.

H. Summary Performance Data

Smith & Nephew GTS Sleeve and GTS Tapered Screw utilize design features and have the same intended use as the predicate device. The in vitro performance testing, material biocompatibility and sterilization validation demonstrate the device is safe, performs as intended, and supports a decision of substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 1 9 2004

Ms. Debra Connors
Regulatory Affairs Specialist
Smith & Nephew, Inc.
Endoscopy Division
150 Minuteman Road
Andover, Massachusetts 01810

Re: K040542
Trade/Device Name: GTS Sleeve and GTS Tapered Screw
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: HWC
Dated: June 9, 2004
Received: June 10, 2004

Dear Ms. Connors:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

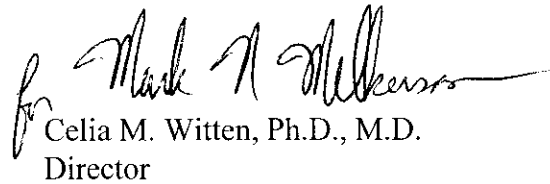
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K040542

Device Name: The Smith & Nephew GTS Sleeve and GTS Tapered Screw

Indications For Use:

The Smith & Nephew GTS Sleeve and GTS Tapered Screw are indicated for fixation of soft tissue grafts during cruciate ligament reconstruction.

for Mark N Milleman

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K040542

Prescription Use ___x___ (Per 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use No (Per 21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)